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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/060,609	04/15/98	OZENBERGER B	AHP98126

HM12/0401

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EXAMINER	
DUFFY, P	
ART UNIT	**PAPER NUMBER**
1645	6

DATE MAILED: 04/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/060,609	Ozenberger et al
	Examiner	Group Art Unit
	Duffy	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-24 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 11, drawn to polynucleotides, host cells and methods of producing the protein, classified in class 536, subclass 23.1.

II. Claims 6-10, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 12, 13 and 20, drawn to methods of using the probes to detect the polynucleotide and diagnostic process therefore classified in class 435, subclass 6.

IV. Claims 14 and 15, drawn to antibodies, classified in class 530, subclass 387.1.

V. Claims 16-19, drawn to methods of using binding reagents to detect the presence of the polypeptide and diagnostic processes therefore, classified in class 435, subclass 7.1.

VI. Claims 21-22, drawn to methods of screening for agents which regulate the activity of the amyloid binding polypeptide, classified in class 435, subclass 7.21.

VII. Claim 23, drawn to method of treating disease by administering the polypeptide, classified in class 514, subclass 12.

VIII. Claim 24, drawn to a transgenic or chimeric animal, classified in class 800, subclass 13.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide product can be used in methods of transformation of cells, in methods of gene therapy, in methods of *in situ* chromosome mapping and in methods of producing the protein product.

Inventions II and (VI or VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be labeled and used in a method of detection of antibodies or the polypeptides can be used as an immunogen to produce antibodies.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a materially different process of using that product such as a therapeutic or as a means for purification of the polypeptide which it specifically binds.

Inventions I, II, IV and VIII are related as products. The claims of Group I are drawn to a polynucleotide, those of Group II are drawn to a polypeptide, that of Group IV to antibodies, and that of Group VIII to an chimeric or transgenic animal. The inventions can be shown to be distinct because they are made by different methods (e.g. recombinant production, in vitro

chemical synthesis, Merrifiled synthesis, injection of an animal with the protein, or injection of the oocyte of an animal) and because they are physically (e.g. nucleic acids, amino acids, and animals) and functionally distinct chemical entities (e.g. encode proteins, mediate biological activity, mediate an immune response and genetically engineered animal as a model of disease). Thus, each product is distinct from each of the other products.

Inventions III, V, VI and VII are related as methods which use the distinct products as described *supra*. The methods are distinct each from the other because they utilize different reagents as defined by the products above, have different goals (e.g. detection of the polynucleic acid, detection of the protein, treatment of disease, screening for agents which regulate activity) and have different method steps and different final outcomes (e.g. detection/diagnosis of disease using polynucleotides or polypeptides, treatment of disease by providing polypeptide, identification of active regulatory agents. For the foregoing reasons each method is distinct from every other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

3. A telephone call was made to Andrea Walsh on February 17, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Patricia A. Duffy, Ph.D.
March 29, 1999

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600